REMARKS

Reconsideration is respectfully requested. This action is in response to the Patent Office communication of August 17, 2004. On entry of this amendment, claims 1 to 21 have been cancelled. New claims 22-48 have been added. Claims 22-48 are now pending.

This response is identical to the response filed on May 21, 2004, except that the claim language of cancelled claims 1-21 has been removed, as required by the Examiner.

Cancellation of certain claims is in no way an admission of or acquiescence to the Examiner's rejection and is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Applicants expressly reserve the right to pursue identical or similar claims in a continuation or divisional patent application.

Election/Restriction

Applicants acknowledge the finality of the Examiner's election of species requirement.

Priority

A. Specification

The Examiner states that the current status of the application is not set forth in the first line of the application, and requests correction. Applicants have amended the specification in accordance with the Examiner's request.

B. Priority Date

The Examiner states that claims directed to SEQ ID NOS: 17-38 are afforded the November 5, 2000 filing date of the present application, not the May 17, 2000 filing date of PCT/IB00/00763.

Claims directed to SEQ ID NOS: 17-38 have a priority date corresponding to the filing date of PCT/IB00/00763. The present application is the U.S. national stage entry of PCT/IB00/00763, filed May 17, 2000. The sequences identified by SEQ ID NOS: 17-38 are fully supported by PCT/IB00/00763 as filed. Specifically, the sequences identified as SEQ ID NOs: 17-38 are disclosed from page 2, line 32 to page 3, line 24. While the corresponding SEQ ID NO: identifiers were added later by amendment dated December 18, 2001, the sequences themselves are fully supported by PCT/IB00/00763. Therefore, the claims directed to SEQ ID NOs: 17-38 are entitled to a priority date of at least May 17, 2000.

Claim Objections

Claims 2, 11 and 21 have been objected to because of various formalities. Since claims 2, 11, and 21 have been cancelled, these grounds for rejection are now moot. Thus, Applicants respectfully request these objections to be withdrawn.

Claim Rejections 35 U.S.C § 112, 1st Paragraph, Written Description

A. Rejection of Claims 1-4, 7-10, 13, 14, 17 and 18

The Examiner has rejected claims 1-4, 7-10, 13, 14, 17 and 18 as allegedly failing to comply with the written description requirement.

Claims 1-4, 7-10, 13, 14, 17 and 18 have been cancelled, rendering the rejection moot. Thus, Applicants respectfully request the rejection be withdrawn.

B. New Claims 22-41 satisfy the written description requirement under 35 U.S.C § 112, 1st Paragraph.

Claims 22, 24-25, 35-36, 38, 41, 42-43, 45 and 48

New claims 22, 24-25, 35-36, 41, 42-43, 45 and 48 now recite methods and compositions that require a modified anti-angiogenic peptide that corresponds to a region of mammalian plasminogen. Applicants have provided extensive written description support for a modified anti-angiogenic peptide comprising a region of mammalian plasminogen, and describe numerous anti-angiogenic peptide species that correspond to a region of mammalian plasminogen. For example, at page 8, lines 22-24, Applicants disclose that "the amino acid sequence of a complete mammalian plasminogen molecule (the human plasminogen molecule), including its kringle 5 region, is presented in (SEQ ID NO: 1)." At page 8, lines 15-22, Applicants disclose that the kringle 5 peptide is one region of mammalian plasminogen. Further, at page 1, lines 26-28, Applicants disclose that "much research has been performed to identify anti-angiogenic molecules," and "one anti-angiogenic molecule of particular interest is plasminogen." In addition, at page 1, lines 28-32, Applicants state "of particular interest is the kringle 5 region of plasminogen and various peptides within the kringle 5 region. Both plasminogen and the kringle 5 region of plasminogen have been shown to interfere with the angiogenic process are thus known as anti-angiogenic peptides." In the paragraph bridging pages 2 and 3 and in the paragraph bridging pages 9 and 10, Applicants provide several examples of kringle 5 peptides and modified kringle 5 peptides, all of which are anti-angiogenic peptides corresponding to regions of mammalian plasminogen. Specific kringle 5 peptides disclosed in the application include peptides identified by SEQ ID NO: 1-16, disclosed, for example, from page 8, line 24 through page 10, line 10. Specific modified kringle 5 peptides include the modified peptides identified by SEQ ID NOs: 17-42, disclosed for example from page 2, line 32 through page 3, line 28, as amended.

Based on the written description support provided by Applicants, it would be clear to one of skill in the art that Applicants had possession of anti-angiogenic peptides corresponding to regions of mammalian plasminogen commensurate with the scope of the claims at the time of filing.

Claims 23, 28, 34, 37 and 44

New claim 23 is drawn to the method that specifically requires "a kringle 5 peptide." New claims 28 and 34 are drawn to a method that specifically requires "a modified kringle 5 peptide comprising a kringle 5 peptide and a reactive group coupled thereto." Claim 37 is drawn to a conjugate that specifically requires "a kringle 5 peptide." Claim 44 is drawn to a composition comprising a conjugate that specifically requires "a kringle 5 peptide." Extensive written description support is provided for these claims as well.

From page 8 line 14 through page 10, line 16 of the specification, Applicants provide an extensive discussion of kringle 5 peptides, include numerous sequences of kringle 5 peptides. At page 8, line 14-24 of the specification, Applicants describe kringle 5 peptides based on their structure and amino acid location in the mammalian plasminogen molecule. From page 8, line 25 through page 9, line 9, Applicants describe numerous kringle 5 peptide variants. In addition, from page 9-10, the specification discloses a number of kringle 5 peptides identified by SEQ ID NOS: 1-16. Further, from page 17, line 18 through page 24, line 21 of the specification, Applicants describe kringle 5 peptide synthesis. Given the extensive discussion of numerous species of kringle 5 peptides, it would be clear to one skilled in the art that Applicants had possession of kringle 5 peptides commensurate with the scope of the claims at the time of filing.

Applicants also provide extensive disclosure of modified kringle 5 peptides from page 10, line 19 to page 20, line 21. From page 10, line 20 through page 12, line 9 of the specification, Applicants describe formation of covalent bonds between modified kringle 5 peptides and functional groups on proteins. From page 12, line 11 through page 17, line 16 of the specification, Applicants describe specific and non-specific labeling of kringle 5 peptides. Beginning at page 17, line 18 of the specification, Applicants disclose synthesis of modified kringle 5 peptides. From page 17, line 18 through page 24, line 21 of the specification, Applicants describe kringle 5 peptide synthesis, and from page 24, line 23 through page 28, line 11, Applicants describe modification of

kringle 5 peptides. Specific modified kringle 5 peptides include the modified peptides identified by SEQ ID NOs: 17-42, disclosed for example from page 2, line 32 through page 3, line 28, as amended. Given the extensive discussion of modified kringle 5 peptides, it would be clear to one skilled in the art the Applicants had possession of modified kringle 5 peptides at the time of filing.

Claims 26-27, 29-33, 39-40, and 46-47

Claims 26-27, 29-33, 39-40 and 46-47 are directed to specific sequences of kringle 5 peptides and modified kringle 5 peptides. All of these specific sequences are described by SEQ ID NO in the specification. It would be clear to one skilled in the art that Applicants had possession of these specific kringle 5 peptide sequences at the time of filing.

Specific Points Raised by the Examiner

In making the prior rejection as to now cancelled claims 1-21, the Examiner asserted that "the written description only sets forth an antiangiogenic peptide, wherein said peptide is a kringle 5 peptide identified as SEQ ID NO:8." This assertion, is clearly incorrect. The specification discloses numerous kringle 5 peptides in addition to SEQ ID NO: 8, as discussed above.

The Examiner also asserted that "the written description is not commensurate with the scope of the claims drawn to all the variants, derivatives, and amino acid combinations of the domain of kringle 5." Claims 22-41, however, are directed to modified kringle 5 peptides and kringle 5 peptides. As discussed above, both modified kringle 5 peptides and kringle 5 peptides are disclosed extensively in the specification.

The Examiner further alleges that "with the exception of SEQ ID NO:2, the skilled artisan cannot the skilled artisan cannot envisions the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred." Again, as discussed above, Applicants have provided detailed structure for both regions of mammalian plasminogen and kringle 5 peptides in addition to SEQ ID NO: 2.

As the Examiner has acknowledged, "applicants are not required to disclose every species encompassed by a genus," and "the description of the genus is achieved by the recitation of a representative number of DNA molecules ...falling within the scope of the claimed genus." Applicants agree with this assessment. As discussed above, the specification provides an extensive disclosure of anti-angiogenic peptides corresponding to a region of mammalian plasminogen. Further, the specification provides numerous representative species of kringle 5 peptides and modified kringle 5 peptides.

In view of the above, Applicants respectfully submit that claims 22 through 48 meet the written description requirement under 35 U.S.C § 112, first paragraph.

Claim Rejections 35 U.S.C § 112, 2nd Paragraph

Claims 1-21 have been rejected by the Examiner as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Without admitting or acquiescing to the Examiner's rejection, Applicants have cancelled 1-21. With respect to these claims, this ground for rejection is therefore moot. Applicants respectfully request that this ground for rejection be withdrawn.

a) "modified anti-angiogenic peptide" and "modified kringle 5 peptide"

The Examiner objected to claims 1, 2 and 19-21 as being vague and indefinite in view of the expressions "modified anti-angiogenic peptide" and "modified kringle 5 peptide."

Applicants respectfully submit that both terms as reintroduced in claims 22-48 are extensively described in the Specification. Applicants describe "modified anti-angiogenic peptides" from page 6, line 10 to page 7, line 6. Applicants describe "modified kringle 5 peptides" from page 10, line 19 to page 20, line 21. Based on the Appellant's disclosure, both claim terms would be

readily understood by any person skilled in the art. These claim terms thus would not be considered vague or indefinite by a person skilled in the art.

Claims 22-48 do not recite any other claim limitations that were the subject of the rejection under 35 U.S.C § 112, 2nd paragraph.

In view of the above, Applicants respectfully submit that new claims 22 to 48 meet requirements under 35 U.S.C § 112, 2nd paragraph.

Claim Rejections 35 U.S.C § 101

Claims 17 and 18 have been rejected, the Examiner alleging that they result in an improper definition of a process.

As indicated above, but without admitting or acquiescing to the Examiner's rejection, Applicants have cancelled claims 17 and 18. This ground for rejection is therefore moot.

Claim Rejections 35 U.S.C § 102(b)

A. Claims 1-5, 7-11, 13-15, 17 and 18

Claims 1-5, 7-11, 13-15, 17 and 18 have been rejected under 35 U.S.C. §102(b) over WO 97/41824 to Davidson et al.

As indicated above, but without admitting or acquiescing to the Examiner's rejection, Applicants have canceled the rejected claims. With respect to the rejected claims, this ground for rejection is therefore moot.

B. New claims 22-41 are patentable under 35 U.S.C § 102(b) over WO 97/41824.

New claims 22-48 are directed to methods of using a modified anti-angiogenic peptide and kringle 5 peptides, as well as conjugates comprising the peptides.

The Cited Reference

WO 97/41824 discloses mammalian kringle 5 fragments and fusion proteins. The reference discloses forming salts of the kringle 5 proteins and peptides, not a modified anti-angiogenic peptide, conjugate, or kringle 5 peptide "comprising a reactive group coupled thereto" as required by the new claims. Further, the reference discloses using maleic acid and succinic acid, not covalently linked maleimido or succinimidyl reactive groups as required by the pending claims. Further, WO 97/41824 only discloses covalently modified kringle 5 sequences having an amino-protecting group and a carboxy protecting groups, none of which are maleimido or succinimidyl groups and none of which are reactive groups.

The Examiner's Rejection of previous claims 1-5, 7-11, 13-15, 17 and 18

The Examiner erroneously alleges that the reference teaches a modified anti-angiogenic peptide with a reactive group coupled thereto, instead of a salt, as disclosed by the reference (page 21). Further, the Examiner asserts that WO 97/41824 teaches that the reactive groups are succinimidyl or maleimido even though the reference only disclosed maleic acid and succinic acid salts. Finally, the Examiner asserts that WO 97/41824 teaches the peptide sequence SEQ ID NO: 8.

The Cited Reference Distinguished

In order to anticipate under § 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). WO 97/41824 fails to teach multiple elements of new claims 22-41, and thus fails to anticipate claims 22-41.

First, WO 97/41824 fails to disclose maleimido or succinimidyl reactive groups. The Examiner erroneously alleges that the maleic acid and succinic acid salts constitute maleimido or succinimidyl reactive groups. WO 97/41824 discloses that maleic acid and succinic acid are two of many pharmaceutically acceptable salts. (page 21 lines 13-38, especially line 38).

Pharmaceutically acceptable salts are not reactive groups, but instead are peptides with maleic and succinic ions in electrostatic association with the peptide. Thus, in the salt form of a peptide, the maleic group or succinic group is a counter-ion in relation with a positively charged group of the peptide. The maleic group or succinic acid salts of WO 97/41824 are not covalently linked to the peptide, and cannot covalently bond a blood component to the peptide to form a conjugate, and are not reactive groups that react with amino groups, hydroxyl groups, or thiol groups. The maleic and succinic ions most certainly do not form stable covalent bonds with blood components.

Second, the reference fails to teach reactive groups that react with amino groups, hydroxyl groups, or thiol groups on blood components, as required by claims 22-30 and 34-41. The maleic acid and succinic acid disclosed by WO 97/41824 are only counter-ions, and not reactive groups. While the reference discloses covalently linked N-protecting or carboxy-protecting groups (see page 9, line 37 to page 12, line 7), none are reactive groups since the protecting groups are intended to protect the sequence and not to react with amino groups, hydroxyl groups, or thiol groups on blood components.

Third, in addition to being salts and not reactive groups, the maleic acid and succinic acid salts disclosed by WO 97/41824 are chemically distinct from the claimed maleimido and succinimidyl reactive groups. The maleic acid and succinic acid disclosed by WO 97/41824 have two oxygen atoms instead of a single nitrogen. Moreover, unlike the maleimido and succinimidyl reactive groups, the maleic acid and succinic acid counter-ions are not cyclic compounds.

Fourth, WO 97/41824 fails to teach or suggest that the reactive groups of the peptides, conjugates, and modified kringle 5 peptides form stable covalent bonds with blood components, as required by claims 22-30 and 34-41. WO 97/41824 discloses only two methods of forming conjugates: "gene therapy" (see page 30, lines 22-30 and page 33, lines 4-6), and "chemically [coupling]...proteins to form conjugates" (see page 35, lines 20-32). Specifically, WO 97/41824 teaches that gene therapy generates fusion proteins, not peptides comprising a succinimidyl or maleimido reactive group. WO 97/41824 fails to teach gene therapy fusion proteins comprising a reactive group that reacts with amino groups, hydroxyl groups, or thiol groups. Moreover, the functional groups provided for forming fusion proteins include "glutaraldehyde, diazotized

benzidine, carbodiimides and p-benzoquinone" (page 35, lines 28-29), none of which are succinimidyl or maleimido reactive groups. In addition, the disclosed agents do not first stably attach to the kringle 5 peptides and then allow a reaction with a blood component, which differs considerably from the teaching of the presently claimed invention. The agents disclosed by WO 97/41824 only attach lysine residues of both the kringle 5 sequence and the protein, while reactive groups of the claimed invention react with amino groups, hydroxyl groups, or thiol groups on blood components. Furthermore, the agents disclosed by WO 97/41824 only react *in vitro*, while the conjugates of the claimed invention can be made both *in vivo* and *ex vivo*.

Finally, the free kringle 5 fragments taught by WO 97/41824 have the *opposite* therapeutic application to the presently claimed invention. The conjugates disclosed in WO 97/41824 are intended for making antibodies or for purification purposes (see page 35, lines 14-26), not for administration for medical treatment. The reference discloses that combining the free kringle 5 fragments with a sustained-release matrix is an alternative to administering free kringle 5 fragments (see page 22, lines 13-27). Sustained release matrices, however, slowly release the kringle 5 fragments. Unlike WO 97/41824, the modified peptides of the presently claimed invention are covalently attached to blood component, and the resulting conjugate provides the therapeutic efficacy and the long lasting effect, not a slowly diminishing effect.

In view of the above arguments, Applicants submit new claims 22 to 41are patentable over WO 97/41824 under 35 U.S.C § 102(b).

Claim Rejections under 35 U.S.C. §102(e)

A. Claims 1-5, 7-11, 13-15, 17 and 21

Claims 1-5, 7-11, 13-15, 17 and 21 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,057,122 (U.S. Patent '122) to Davidson et al., filed May 5, 1997, issued May 2, 2000). The disclosure of U.S. Patent '122 is identical to the disclosure of WO 97/41824. The arguments advanced in response to the rejection over WO 97/41824 under 35 U.S.C. §102(e) also apply to the present rejection.

As indicated above, but without admitting or acquiescing to the Examiner's rejection, Applicants have cancelled claims 1-5, 7-11, 13-15, 17 and 21. This ground for rejection is therefore moot. Applicants respectfully request that it be withdrawn.

B. New claims 22-48 are patentable under 35 U.S.C § 102(e) over Patent '122.

New claims 22-48 are directed to methods of using a modified anti-angiogenic peptide and kringle 5 peptides, as well as conjugates comprising the peptides.

The Examiner's Rejection

The Examiner alleges that U.S. Patent '122 teaches that "kringle 5 peptide fragments ... may be combined with pharmaceutically acceptable excipients or carriers to form therapeutic compositions" and cites "Abstract; column 16, lines 46; column 17, line 57; column 19, lines 18-29; column 20, line 63; and column 21, line 5" for support. The Examiner's further alleges that "the compounds of the disclosed invention may include a reactive group such as maleic acid or succinic acid," pointing to column 18, lines 5-43 for support.

The Cited Reference

Like WO 97/41824, U.S. Patent '122 discloses mammalian kringle 5 fragments and fusion proteins. U.S. Patent '122 discloses forming salts of the kringle 5 proteins and peptides, not a modified antiangiogenic peptide, conjugate, or kringle 5 peptide "comprising a reactive group" as required by the new claims, or a method of administering or using them. Further, the reference discloses using maleic acid and succinic acid not covalently linked to maleimido or succinimidyl reactive groups. U.S. Patent '122 only discloses covalently modified kringle 5 sequences having an amino-protecting group and a carboxy-protecting group, none of which are maleimido or succinimidyl groups and none of which are reactive groups.

The Cited Reference Distinguished

As previously indicated, in order to anticipate a claim under 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). To the extent that the Examiner's rejection applies to new claims 22-48, U.S. Patent '122 fails to teach multiple elements of new claims 22-48.

First, as stated in the response to the 102(b) rejection above and reiterated here, U.S. Patent '122 fails to disclose maleimido or succinimidyl reactive groups. The Examiner erroneously alleges that the pharmaceutically acceptable salts disclosed in U.S. Patent '122 maleic acid and succinic acid salts constitute maleimido or succinimidyl reactive groups. U.S. Patent '122 discloses that maleic acid and succinic acid are two of many pharmaceutically acceptable salts. (Col. 18 lines 5-43, especially line 43). As pointed out in the response to the rejection over WO 97/41824 and reiterated here, pharmaceutically acceptable salts are not reactive groups, but instead are peptides with maleic and succinic ions in electrostatic association with the peptide. Thus, in the salt form of a peptide, the maleic group or succinic group is a counter-ion in relation with a positively charged group of the peptide. The maleic group or succinic acids of U.S. Patent '122 are not covalently linked to the peptide, and cannot covalently bond a blood component to the peptide to form a conjugate. Furthermore, the maleic and succinic ions are not reactive groups that react with amino groups, hydroxyl groups, or thiol groups. The maleic and succinic ions most certainly do not form stable covalent bonds with blood components.

Second, like WO 97/41824, U.S. Patent '122 fails to teach reactive groups that react with amino groups, hydroxyl groups, or thiol groups on blood components, as required by claims 22-30 and 34-41. The maleic acid and succinic acid disclosed by U.S. Patent '122 are only counter-ions referred to as a "protecting group," and not reactive groups as defined in the present application. While the reference discloses covalently linked N-protecting or carboxy-protecting groups, none are reactive groups since the protecting groups are intended to protect the sequence and not to react with amino groups, hydroxyl groups, or thiol groups on blood components.

Third, the maleic acid and succinic acid salts disclosed by U.S. Patent '122 are chemically distinct from the claimed maleimido and succinimidyl reactive groups. The maleic acid and succinic acid disclosed by U.S. Patent '122 have two oxygens instead of a single nitrogen. Moreover, unlike the maleimido and succinimidyl reactive groups, the maleic acid and succinic acid counter-ions are not cyclic compounds.

Fourth, U.S. Patent '122 fails to teach or suggest that the reactive groups of the peptides, and modified kringle 5 peptides, form stable covalent bonds with blood components, as required by claims 22-30 and 34-41. U.S. Patent '122 discloses only two methods of forming conjugates: "gene therapy" (see Col. 26 lines 46-61), and "chemically [coupling] ...proteins to form conjugates" (see Col. 29 line 66 – Col. 30 line 34). U.S. Patent '122 teaches that gene therapy generates fusion proteins, not peptides comprising a succinimidyl or maleimido reactive group. U.S. Patent '122 fails to teach gene therapy fusion proteins comprising a reactive group which reacts with amino groups, hydroxyl groups, or thiol groups. Moreover, the functional groups provided for forming fusion proteins include "glutaraldehyde, diazotized benzidine, carbodiimides and p-benzoquinone" (Col. 30 lines 13-14), none of which are succinimidyl or maleimido reactive groups. In addition, the disclosed agents are not first stably attached to the kringle 5 peptides and then allow a reaction with a blood component, which differs considerably from claims 22-30 and 34-41. The agents disclosed by U.S. Patent '122 only attach lysine residues of both the kringle 5 sequence and the protein, while reactive groups of the claimed invention react with amino groups, hydroxyl groups, or thiol groups on blood components. Furthermore, the agents disclosed by U.S. Patent '122 only react in vitro, while the conjugates of the claimed invention can be made both *in vivo* and *ex vivo*.

Finally, the free kringle 5 fragments taught by U.S. Patent '122 have the *opposite* therapeutic application to the presently claimed invention. The conjugates disclosed in U.S. Patent '122 are intended for making antibodies or for purification purposes (see Col. 29, lines 57-65), not for administration for medical treatment. U.S. Patent '122 discloses that combining the free kringle 5 fragments with sustained-release matrices is an alternative to administering free kringle 5 fragments (see Col. 18, lines 44-62). Sustained release matrices, however, slowly release the kringle 5 fragments. Unlike U.S. Patent '122, the modified peptides of the presently claimed invention are

covalently attached to blood component and the resulting conjugate provides the therapeutic efficacy and the long lasting effect, not a slowly diminishing effect.

In view of the above arguments, claims 22 to 48 are patentable over U.S. Patent '122 under 35 U.S.C § 102(e).

Double Patenting

The Examiner has provisionally rejected claims 1-16 and 19-21 under U.S.C § 101 as claiming the same invention as that of claims 19-21 of the copending Application No. 09/657,431. The Examiner has also provisionally rejected claims 17 and 18 under the judicially created doctrine of obviousness-type double patenting over the same claims. Claims 1-16 and 19-21 have been canceled rendering the provisional rejections as to those claims moot. In the event any of new claims 22-48 become subject to similar such provisional rejections, applicants intend to file a terminal disclaimer or otherwise cancel or amend conflicting claims, as warranted, upon indication that such claims are otherwise allowable.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of

such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **500862002200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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